DEPARTMENT OF HEALTH & HUMAN SERVICES
New York District

Food & Drug Administration
300 Pearl Street, Suite 100
Buffalo, NY 14202

MB102v1

October 27, 1999

WARNING LETTER NYK 2000-06

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. David J. Armstrong Jr., Administrator
Little Falls Hospital
140 Burwell Street
Little Falls, New York 13365

RE: Facility ID Number 120733

Dear Mr. Armstrong:

We are writing to you because on September 22, 1999, your facility was inspected by a representative of the New York State Department of Health, acting on behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following repeat Level 2 finding at your facility:

- ***Processor QC records were missing 6 out of 22 days of operation in April 1999, or 27% of the time, for the [redacted] processor.***

The specific problem noted above appeared on your MQSA Facility Inspection Report that your facility received at the close of the inspection. This problem is identified as a repeat Level 2 because it identifies a failure to meet a significant MQSA requirement and it indicates a failure to implement permanent correction of a problem found during your pervious inspection.

Because this condition may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, it represents a violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction; charging your facility for the cost of on-site monitoring; assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with MQSA standards; suspension or revocation of your facility's FDA certificate; and/or obtaining a court injunction against further mammography.

In addition, your response to this letter should also address the Level 2 findings that were listed on the inspection report provided at the close of the inspection. The Level 2 findings are:

- ***Mammograms were processed in the [redacted] processor when it was out of limits on 2 days.***
- ***Processor QC records were missing on 2 consecutive days.***

It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date that you receive this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- sample records that demonstrate proper record keeping procedures.

Please submit your response to the attention of Lisa M. Utz, Compliance Officer, U.S. Food and Drug Administration, 300 Pearl Street, Olympic Towers, Suite 100, Buffalo, New York 14202.

Finally, you should understand there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, Maryland 21045-6057 (1-800-838-7715), or through the Internet at http://www.fda.gov.

If you have questions about mammography facility requirements, or about the content of this letter, please feel free to contact Murray L. Kurzman, Radiation Programs Manager, at (516) 921-2035.

Sincerely,

Brenda J. Holman
District Director